PATENT
Docket No.: **176/61702 (1265)**

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants	:	Fay et al.	)	Examiner: Marsha M. Tsay
Serial No.	:	10/581,471	)	
Cnfrm. No.	:	3888	)	Art Unit: 1656
Filed	:	December 2, 2004	)	
For	:	RECOMBINANT FACTOR VIII HAVING INCREASED SPECIFIC ACTIVITY	)	

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This submission is in response to the June 24, 2008, office action, imposing a revised written restriction requirement. This response is being filed with a Petition for a Three Month Extension of Time.

In response to the restriction requirement, applicants hereby elect Group I (i.e., claims 1-6, 9, 11-13, and 19-22) with traverse.

Applicants traverse this restriction on the basis that unity of invention does exist. The U.S. Patent and Trademark Office ("PTO") asserts on page 2 of the office action that unity is lacking based on U.S. Patent No. 5,859,204 to Lollar et al. ("Lollar"), citing Table 1 as identifying several domains to be mutated. Applicants respectfully disagree. Lollar is primarily concerned with chimeric (mutant) forms of factor VIII that have reduced reactivity to inhibitory antibodies while retaining procoagulant activity, and the regions identified in Table I of Lollar are identified for that purpose. Even if the mutation sites identified in Lollar are in the A2 subunit, the PTO has not demonstrated that these sites are in or near at least one calcium binding site. All that the PTO has done is demonstrate that the residues to be modified by Lollar are in the A2 domain. Moreover, the PTO has also failed to demonstrate where Lollar teaches that the "resulting recombinant factor VIII has increased

specific activity relative to wild-type factor VIII." Because the PTO has failed to demonstrate where Lollar teaches either of these limitations, Lollar cannot destroy unity in this invention.

Further, the nucleic acid molecule of Group II, and its use, includes all limitations of the product of Group I (i.e., claim 23 recites an "isolated nucleic acid molecule encoding a recombinant factor VIII according to claim 1"). Therefore, the protein and nucleic acid molecules share unity for the reasons noted above, and all claims of Groups I and II should be examiner together.

Because the subject matter of Groups III-VII encompass the combination of the various features with the point mutation in or near at least one calcium binding site of a wild-type factor VIII, where the resulting recombinant factor VIII has increased specific activity relative to wild-type factor VIII (as recited in claim 1, Group I), Groups III-VII are joined together by the technical feature recited in claim 1. In other words, claim 1 is a linking claim that links together the distinct combinations of Groups III-VII by their shared technical feature. For this reason, restriction between Groups I and III-VII is improper and should be withdrawn.

Finally, restriction between the product claims of Group I and its use, encompassed in Group VIII, is improper. Claim 48 recites a method of treating an animal for hemophilia A that includes administering "the recombinant factor VIII according to claim 1." Thus, the claimed use includes all limitation of the product of Group I, and as such unity exists between the product and its use. For this reason, all claims of Groups I and VIII should be examined together.

For all of the foregoing reasons, the lack of unity rejection should be withdrawn in its entirety.

If any further action is required by the applicants, then the applicants invite the examiner to contact the undersigned attorney at the telephone number listed below.

Respectfully submitted,

Date: October 23, 2008

/Edwin V. Merkel/
Edwin V. Merkel
Registration No. 40,087

Nixon Peabody LLP
1100 Clinton Square
Rochester, New York 14604
Telephone: (585) 263-1128
Facsimile: (585) 263-1600